



COLOR PIGMENTS MANUFACTURERS ASSOCIATION, INC.

201-16303

August 1, 2006

Mr. Jeffrey Taylor
U.S. Environmental Protection Agency
EPA East Building
Room 4410H (MC7405)
1200 Pennsylvania Ave, NW
Washington, DC 20004
202.564.8828

Dear Mr. Taylor:

On June 9, 2006 CPMA submitted to you six test plans prepared by committees of the Color Pigments Manufacturers Association, Inc. (CPMA) under EPA's High Production Volume Chemical Testing Program:

- Test Plan for 6-Amino-4-chloro-m-toluenesulfonic acid (2B Acid) and 2-Amino-5-chloro-ptoluenesulfonic acid (C Amine),
- Test Plan 3,3' Dichlorobenzidine Dihydrochloride,
- Test Plan for C. I. Pigments Violet 19, Red 122, and Dihydro Quinacridone,
- Test Plan for C. I. Pigment Red 48 (Barium), C.I. Pigment Red 48 (Calcium) and C.I. Pigment Red 52 (Calcium),
- Test Plan for C.I. Pigment Yellow 14, and
- Test Plan for C. I. Pigment Red 49 (Barium)

The test plans were formatted incorrectly and were actually earlier drafts. As a result, we are submitting the revised test plans.

Two test plans have already been posted on the EPA web site: Test Plan for C. I. Pigment Red 49 (Barium) and Test Plan for C6-Amino-4-chloro-m-toluenesulfonic acid (2B Acid) and 2-Amino-5-chloro-ptoluenesulfonic acid (C Amine). Your removal of these two tests plans from the site and replacing them with the enclosed revised test plans is appreciated.

The remaining test plans that were previously sent and have not yet been posted should be disregarded, and replaced with the corrected versions.

Thank you for your attention to this.

Sincerely,

J. Lawrence Robinson
President

August 8, 2006

Dear NCIC,

Please replace the previous 6 CPMA test plan and robust summary submissions (AR201-16298 through AR201-16303) from June 2006 with these newly corrected 6 CPMA test plan and robust summary submissions. CPMA phoned me to say that no substantial information was changed; only the formatting was corrected. Please give these new submissions the same AR numbers that you had previously used for them, and also process this cover page of mine along with CPMA's new cover page that they have attached to the new materials.

Thank you,
Jeffrey Taylor

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201-16303A

HIGH PRODUCTION VOLUME (HPV) CHALLENGE PROGRAM

TEST PLAN
FOR
C.I. Pigment Violet 19
(CAS NO.: 1047-16-1)
AND
C.I. Pigment Red 122
(CAS NO. 980-26-7)
AND
Dihydro Quinacridone
(CAS NO. 5862-38-4)

PREPARED BY:
COLOR PIGMENTS MANUFACTURERS ASSOCIATION, INC.
QUINACRIDONE COMMITTEE

June, 2006

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OVERVIEW

The Quinacridone Committee ("QC") of the Color Pigment Manufacturers Association, Inc. (CPMA) and its member companies hereby submits for review and public comment the test plan for C.I. Pigment Violet 19 (CAS NO.: 1047-16-1) and C.I. Pigment Red 122 (CAS NO. 980-26-7) and Dihydro Quinacridone under the Environmental Protection Agency's (EPA) High Production Volume (HPV) Challenge Program. It is the intent of the QC and its member companies to use existing data, and predictive computer models to adequately fulfill the Screening Information Data Set (SIDS) for the various physicochemical, environmental fate, ecotoxicity test, and human health effects endpoints.

C.I. Pigment Violet 19 (CAS NO.: 1047-16-1) and C.I. Pigment Red 122 (CAS NO. 980-26-7) and Dihydro Quinacridone are stable solids. These pigments are suitable candidates for the pigmentation of high grade industrial finishes. Systems containing quinacridone pigments include original automotive finishes and refinishes, weatherfast emulsion paints such as house paints, plastics, high grade printing inks for purposes such as metal decorating and poster printing, and weatherfast textile printing, as well as spin dyeing. These chemicals are stable in neutral solutions, and are considered as "not readily biodegradable". Dihydro Quinacridone is a site limited intermediate which is used specifically for the manufacture of finished quinacridone pigments. There is no further exposure to this substance either in the workplace or in commercial products. The substance is structurally similar to the color pigments and only exists in a small number of closed production systems.

TEST PLAN SUMMARY

(CAS NO.: 1047-16-1, 980-26-7 and 5862-38-4)	Information	OECD Study	Other	Estimation	GLP	Acceptable	New Testing Req.
STUDY	Y/N	Y/N	Y/N	Y/N	Y/N	Y/N	Y/N
PHYSICAL-CHEMICAL DATA							
Melting Point	Y	-	-	Y	N	Y	N
Boiling Point	N/A	-	-	Y	N	Y	N
Vapor Pressure	Y	-	-	Y	N	Y	N
Partition Coefficient	N/A	-	-	Y	N	Y	N
Water Solubility	Y	-	-	Y	N	Y	N
ENVIRONMENTAL FATE ENDPOINTS							
Photodegradation	Y	N	-	Y	N	Y	N
Stability in Water	N/A	N	-	-	-	Y	N
Biodegradation	Y	N	-	-	Y	Y	N
Transport between Environmental Compartments (Fugacity)	Y	N	-	Y	N	Y	N
ECOTOXICITY							
Acute Toxicity to Fish	Y	N	-	-	Y	Y	N
Acute Toxicity to Aquatic Invertebrates	Y	N	-	-	Y	Y	N
Toxicity to Aquatic Plants	Y	N	-	-	-	Y	N
TOXICOLOGICAL DATA							
Acute Toxicity	Y	N	Y	-	-	Y	N
Repeated Dose Toxicity	Y	N	Y	-	-	Y	N
Genetic Toxicity – Mutation	Y	N	Y	-	-	Y	N
Genetic Toxicity – Chromosomal Aberrations	Y	N	Y	-	-	Y	N
Developmental Toxicity	Y	N	Y	-	-	Y	N
Toxicity to Reproduction	Y	N	Y	-	-	Y	N

TEST PLAN DESCRIPTION FOR EACH SIDS ENDPOINT

A. Physicochemical

Melting point -	A value for this endpoint was obtained from a reputable journal published values from reputable journals and estimations.
Boiling Point -	A value for this endpoint was obtained using a computer estimation-modeling program within EPIWIN
Vapor Pressure -	A value for this endpoint was obtained using a computer estimation-modeling program within EPIWIN.
Partition Coefficient -	This endpoint cannot be determined due to the lack of solubility for these compounds in both octanol and water.
Water Solubility -	A value for this endpoint was obtained using a computer estimation-modeling program within EPIWIN.
Conclusion:	All end points have been satisfied by utilizing data obtained from the various physical chemical data modeling programs within EPIWIN or using measured values. The results of the various computer estimation models within EPIWIN have been noted by the Agency as acceptable in lieu of actual data or values identified from textbooks. No new testing is required.

B. Environmental Fate

Photodegradation -	A value for this endpoint was obtained using AOPWIN, a computer estimation-modeling program within EPIWIN (1).
Stability in Water -	A value for this endpoint was obtained from an acceptable estimation.
Biodegradation -	A value for this endpoint was obtained from an acceptable estimation.
Fugacity -	A value for this endpoint was obtained using the EQC Level III partitioning computer estimation model within EPIWIN.
Conclusion:	All endpoints have been filled with data utilizing acceptable methodologies and of sufficient quality to fulfill these endpoints. No new studies are being proposed.

C. Ecotoxicity Data

Acute Toxicity to Fish -	This endpoint is filled by data from an acceptable study.
Acute Toxicity to Aquatic Invertebrates -	This endpoint is filled by data from an acceptable estimation
Toxicity to Aquatic Plants	This endpoint is filled by data from an acceptable estimation
Bioaccumulation	Estimations of bioaccumulation and log kow values are cannot reasonable be obtained for these compounds due to there insolubility in both water and octanol.
Conclusion:	All endpoints have been satisfied with data from studies that were conducted using studies

or acceptable estimations. In total, these currently available studies are of sufficient quality to conclude that no additional testing is needed.

D. Toxicological Data

Acute Toxicity - This endpoint is filled by oral exposure data from various published and unpublished references to studies. Data for Skin sensitization, skin irritation and eye irritation are also available.

Repeat Dose Toxicity - This endpoint is filled by data from a several studies for the C.I. Pigment Violet 19

Genetic Toxicity-
Mutation - This endpoint is filled by acceptable studies.

rration - This end point is filled by acceptable studies for C.I. Pigment Violet 19 .

Developmental
Toxicity - This endpoint is filled by data from long term feeding studies for C.I. Pigment Violet 19.

Reproductive
Toxicity - This endpoint is filled by data from an acceptable studies.

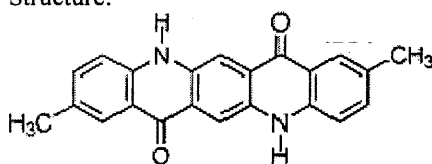
Conclusion: All endpoints have been satisfied with data which are of sufficient quality to conclude that no additional testing is needed.

Rationalization for Test Plan Grouping

As a means to reduce the number of tests that may be conducted the EPA allows for the use of data from structurally similar compounds to characterize specific SIDS endpoints (US EPA 1999a). Accordingly, the QC believes that data from the available studies for C.I. Pigment Violet 19 (CAS NO.: 1047-16-1) and C.I. Pigment Red 122 (CAS NO. 980-26-7) and Dihydro Quinacridone meets the needed criteria for use as a surrogate test grouping in the completion of some SIDS endpoints. All of these substances are based on dioxotetrahydroquinolinoacridine. As is readily seen by their structures below, C.I. Pigment Violet 19 and C.I. Pigment Red 122 only differ by the substitution of a structurally similar molecule. Dihydroquinacridone is a colored intermediate with a similar structure. These minor differences do not significantly alter the basic physicochemical properties or the basic biological effects. The three compounds have a similar acute toxicity value. Accordingly, data from all three compounds have been used when necessary to fulfill SIDS endpoints.

Common Name: C.I. Pigment Red 122

Structure:

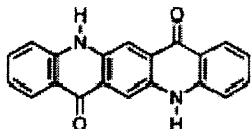


Chemical Name: Quino(2,3-b)acridine-7,14-dione,5,12-dihydro-2,9-dimethyl (CAS No. 980-26-7)

Melting Point: 440 °C
Boiling Point: Solid
Density 11.6 to 12.5 Pounds Per U.S. Gallon, NPIRI
Acute Toxicity: LD50>5000 mg/kg, NPIRI
Water Solubility : mg/l at 20 °C

Common Name C.I. Pigment Violet 19

Structure:

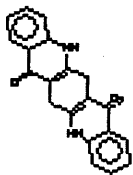


Chemical Name Quino(2,3-b)acridine-7,14-dione,5,12-dihydro (CAS No. 1047-16-1)

Melting Point 310 >400 NPIRI °C Company supplied data
Boiling Point: Solid
Density 12.6 to 14.8 Pounds Per U.S. Gallon
Acute Toxicity: LD50 >5000 mg/kg, NPIRI, LD50 > 10,000 mg/kg Company data,
Water Solubility :

Common Name Dihydro Quinacridone

Structure



Chemical Name (CAS NO. 5862-38-4)

Melting Point
Boiling Point: Solid
Acute Toxicity: Company data
Water Solubility :

SIDS DATA SUMMARY

Physical Chemical Endpoints

Data assessing the various physicochemical properties (melting point, boiling point, vapor pressure, partition coefficient, and water

Data assessing the various physicochemical properties (melting point, boiling point, vapor pressure, partition coefficient, and water solubility) for the quinacridones were obtained from existing data and estimations using the models within EPIWIN where appropriate. These data indicate that the quinacridones are stable solids at room temperature, are largely insoluble in octanol and are also insoluble in water .

Environment

For the environment, data assessing the various environmental fate properties for the quinacridones were obtained from estimations using the models within EPIWIN.. These data indicate that the quinacridones are stable solids at room temperature, are largely insoluble in octanol and is also insoluble in water. As a result, the quiacridones represent with high probability a low potential risk to the aquatic environment.

Acute Toxicity

After single oral administration of C.I. Pigment Red 122 to rats the compound can be considered to be of low toxicity. The LD50-values determined for C.I. Pigment RED 122 was > 5000 mg/kg body weight. The LD50-values determined for C.I. Pigment Violet 19 was > 5000 mg/kg body weight. Pigments Red 122 and Violet 19 do not irritate the skin and eyes in respective tests with rabbits. and does not show evidence of a sensitizing effect in the modified Maximization Test with guinea pigs. The potential to induce toxicity in mammalian species following acute oral exposure is very low.

Human Health

Pigment Violet 19 was evaluated for toxicity in Fisher 344 rats by oral administration for 33 days. None of the study animals died on test. Clinically, high dose (10%) animals demonstrated significant body weight gain compared to controls, which appeared to be associated with corresponding increase in food intake. It appeared that these animals tried to compensate by overeating for the decrease in nutritional intake in the 10% pigment diet. These animals, and to a lesser extent the 5% and 1% dose level animals, also had purple tinged fur, apparently as a result from coming in contact with the color pigment in feed hoppers. No other clinical sign were seen in the animals. Clinical pathology, ophthalmology, cytogenetic analysis, organ weights, and gross and tissue morphology examinations failed to detect the toxicity associated with Pigment Violet 19. (A very slight but statistically significant increase in methemoglobin levels was seen for the high dose female rats at week 2, but in neither sex at week 4. Not considered related to Pigment Violet 19 treatment.) In general, under the conditions of the study, toxicity was not observed following the administration of up to 10% Pigment Violet 19 in the diet of Fisher 344 rats for 33 days. Absorption, Distribution and Excretion studies and a an analysis by whole body autoradiography in rats consistently indicate that C.I. Pigment Violet 19 is excreted from the body in the feces intact.

Carcinogenicity

Animal data:

Ames tests were performed with six different crystal forms of C.I.Pigment Violet 19. No mutagenic activity was seen with any of the various crystal forms. Reputable textbooks in the industry indicate that C.I. Pigment 122 has also been tested under the Ames test and found to be negative. Ames testing for dihydroquinacridone.

An analysis of the unscheduled DNA synthesis was performed with C.I. Pigment Violet 19. Rats were administered 1%, 5 % and 10% in the diet for 14 days. The study concluded that C.I. Pigment Violet 19 had no effect on unscheduled DNA synthesis under the conditions of the study.

An in vivo mouse micronucleus and lymphoma cell mutation assay has also been performed with negative mutagenicity results.

Reproductive Toxicity

AN OECD 211 Daphnia Magna reproduction assay done for C.I. Pigment Red 122 under GLP conditions found no differences in the onset of brood production observed in the concentration group in comparison to the control. The reproduction rate in the concentration group showed no statistically significant changes in comparison to the control. Given the extensive absorption, distribution and excretion studies and analysis by whole body autoradiography that have been performed for C.I. Pigment Violet 19, which indicate that the compound is effectively excreted in the feces and is not absorbed or metabolized, there is no benefit seen in conducting yet another reproductive or reproductive and developmental assay on these color pigments and related colored intermediates.

Conclusion

All endpoints have been satisfied with sufficient data and estimates, which are of sufficient quality to conclude that no additional testing is needed. Since these substances are extremely stable and insoluble in water, ink formulations or other uses such as paints and plastic formulations and octanol and since these substances are encapsulated in all end-use applications, exposure to these products in use is limited.

EVALUATION OF DATA FOR QUALITY AND ACCEPTABILITY

The collected data were reviewed for quality and acceptability following the general US EPA guidance (3) and the systematic approach described by Klimisch *et al.* (4). These methods include consideration of the reliability, relevance and adequacy of the data in evaluating their usefulness for hazard assessment purposes. This scoring system was only applied to ecotoxicology and human health endpoint studies per EPA recommendation (5). The codification described by Klimisch specifies four categories of reliability for describing data adequacy. These are:

1. **Reliable without Restriction:** Includes studies or data complying with Good Laboratory Practice (GLP) procedures, or with valid and/or internationally accepted testing guidelines, or in which the test parameters are documented and comparable to these guidelines.
2. **Reliable with Restrictions:** Includes studies or data in which test parameters are documented but vary slightly from testing guidelines.
3. **Not Reliable:** Includes studies or data in which there are interferences, or that use non-relevant organisms or exposure routes, or which were carried out using unacceptable methods, or where documentation is insufficient.
4. **Not Assignable:** Includes studies or data in which insufficient detail is reported to assign a rating, e.g., listed in abstracts or secondary literature.

REFERENCES

1. EPIWIN, Version 3.10, Syracuse Research Corporation, Syracuse, New York.
2. US EPA. (1999). The Use of Structure-Activity Relationships (SAR) in the High Production Volume Chemicals Challenge Program. OPPT, EPA.
3. USEPA (1998). 3.4 Guidance for Meeting the SIDS Requirements (The SIDS Guide). Guidance for the HPV Challenge Program. Dated 11/2/98.
4. Klimisch, H.-J., Andreae, M., and Tillmann, U. (1997). A Systematic Approach for Evaluating the Quality of Experimental Toxicological and Ecotoxicological Data. *Regul. Toxicol. Pharmacol.* 25:1-5.
5. USEPA. 1999. Determining the Adequacy of Existing Data. Guidance for the HPV Challenge Program. Draft dated 2/10/99.

I. General Information

CAS Number: C.I. Pigment Violet 19, (CAS No. 1047-16-1)

Name: Quino(2,3-b)acridine-7,14-dione,5,12-dihydro

CAS Number: C.I. Pigment Violet 122, (CAS No. 980-26-7)

Name: Quino(2,3-b)acridine-7,14-dione,5,12-dihydro-2,9-dimethyl

CAS Number: (CAS NO. 5862-38-4)

Name: Dihydro Quinacridone

II. Physical-Chemical Data

A1. Melting Point

Test Substance

Test substance: Quino(2,3-b)acridine-7,14-dione,5,12-dihydro

Remarks:

Method

Method: Measured

Remarks:

Results

Melting point value: >400 °C

Remarks:

References

Other

Anliker R. and Moser P. , The Limits of Bioaccumulation of Organic Pigments in Fish: Their Relation to the Partition Coefficient and the Solubility in Water and Octanol, Ecotox. And Envir. Saf. 13, Pp. 43-52 (1987) Data is consistent with melting points for the class of pigments and other available measurements,

A2. Melting Point

Test Substance

Test substance: Quino(2,3-b)acridine-7,14-dione,5,12-dihydro-2,9-dimethyl

Remarks:

Method

Method: Adapted Joback Method

Remarks:

Results

Melting point value: 349 °C

Remarks:

References

EPIWIN v 3.10, Syracuse Research Corporation, Syracuse, New York

Other

Data is consistent with melting points for the class of pigments and other available measurements.

A2. Melting Point

Test Substance

Test substance: Dihydro Quinacridone

Remarks:

Method

Method: Esitimate, Adapted Joback method

Remarks:

Results

Melting point value: 349.84 °C

Remarks:

References

EPIWIN v 3.10, Syracuse Research Corporation, Syracuse, New York

Other

Data is consistent with melting points for the class of pigments and other available measurements.

B. Boiling Point
Test Substance

Test substance: SOLID N/A
Remarks:

Method

Method:
Remarks:

Results

Boiling point value:
Remarks:

References

Other

C1. Vapor Pressure

Test Substance

Test substance: Quino(2,3-b)acridine-7,14-dione,5,12-dihydro
Remarks:

Method

Method: Estimation
Remarks: Modified Grain method

Results

Vapor pressure value: 1.13 E-010 mmHg
Temperature:
Remarks:

References

MPBPWIN v1.40 in EPIWIN v 3.10, Syracuse Research Corporation,
Syracuse, New York

Other

C2. Vapor Pressure

Test Substance

Quino(2,3-b)acridine-7,14-dione,5,12-dihydro-2,9-dimethyl

Remarks:

Results

Vapor pressure value: 2.14 E-011 mm Hg
Temperature:

Remarks:

Method

Method:
Remark:

Estimation
Modified Grain method

References
York

MPBPWIN v 1.40 in EPIWIN v 3.10, Syracuse Research Corporation, Syracuse, New

Other

D. Partition Coefficient**Test Substance**

Test substance: Quino(2,3-b)acridine-7,14-dione,5,12-dihydro

Remarks:

Method

Method: Octanol Solubility Determination
Remarks: GLP \1996\ Guideline 40 CFR 796

Results

Solubility: .808 mg/L at 20 °C
Remarks:

References

Corning Hazleton, CHW 6623-105, 1996, Log Kow partition coefficient cannot be determined for this compound, solubility in water and octanol are too low to produce a meaningful value.

Other**E. Water Solubility****Test Substance**

Test substance: Quino(2,3-b)acridine-7,14-dione,5,12-dihydro

Remarks:

Method

Method: Estimated
Remarks:

Results

Value: <.808 mg/L
Temperature: 20 °C
Description:
Remarks: Extremely Low Solubility

References

Corning Hazleton, CHW 6623-105, 1996, Log Kow partition coefficient cannot be determined for this compound, solubility in water and octanol are too low to produce a meaningful value.

Other

III. Environmental Fate Endpoints

A. Photodegradation

Test Substance

Test substance: Quino(2,3-b)acridine-7,14-dione,5,12-dihydro

Remarks:

Method

Method: Estimate

Test type: Water\sunlight

Remarks:

Results

Temperature:

Degradation Rate

: Half-life .642 hours

Ozone reaction:

Remarks:

Conclusions

[Estimate only applies to minute soluble fraction]

References

AOPWIN v 1.91, Syracuse Research Corporation, Syracuse, New York

Other

A2. Photodegradation

Test substance: Quino(2,3-b)acridine-7,14-dione,5,12-dihydro-2,9-dimethyl

Remarks:

Method

Method: Estimate
Test type: Water/sunlight
Remarks:

Results

Temperature:
Hydroxyl radicals reaction
OH Rate constant:
Half-life .641 hours
Ozone reaction:
Remarks:

Conclusions [Estimate only applies to minute soluble fraction]

References AOPWIN v 1.91, Syracuse Research Corporation, Syracuse, New York

Other

B. Stability in Water**Test Substance**

Test substance: Quino(2,3-b)acridine-7,14-dione,5,12-dihydro

Remarks:

Method

Method:

Test type:

GLP:

Remarks:

Results

Half-life:

Percent hydrolyzed in
5 days (120 hs)

at 50 °C :

Remarks:

Conclusions**Data Quality**

Remarks:

References**Other**

Due to extremely low solubility, hydrolysis in water for quinacridone pigments cannot be estimated or measured accurately at this time. See HYDROWIN v 1.67 Syracuse Research Corporation, Syracuse, New York

C. Biodegradation

Test Substance

Test substance: Quino(2,3-b)acridine-7,14-dione,5,12-dihydro

Remarks:

Method

Method: Estimation

Test type:

GLP:

Year:

Remarks:

Results

Results: noreadily biodegradable

Remarks:

Conclusions

Results apply to all three quinacridone pigments.

Data Quality

Remarks:

References

EPI Suite HYDROWIN v 4.02 Syracuse Research Corporation, Syracuse, New York, Anliker R., and Clarke, E.A. Ecology and Toxicology of Synthetic Organic Pigments, Chemosphere, Vol. 9, pp. 595-609 (1980)

Other

D. Transport between Environmental Compartments (Fugacity)

Test Substance

Test substance: Quino(2,3-b)acridine-7,14-dione,5,12-dihydro

Remarks:

Method

Test type: Estimation

Model used: Level III Fugacity Model; EPIWIN:EQC from Syracuse Research Corporation

Remarks:

Results

Model data and results: Distribution (%)

Air	5.15 E-007
Water	37.1
Soil	62.8
Sediment	.0897

Remarks:

Since no experimental values were available the physical chemical values utilized in this model were default parameters from within EPIWIN.

Conclusions

References

Meylan, W. (1993). User's Guide for the Estimation Programs Interface (EPI), Version 3.10, Syracuse Research Corporation, Syracuse, New York 13210. The Level III model incorporated into EPIWIN is a Syracuse Research Corporation adaptation of the methodology described by Mackay *et al.* 1996; *Environ. Toxicol. Chem.* **15**(9), 1618-1626 and 1627-1637.

Other

D2. Transport between Environmental Compartments (Fugacity) Test Substance

Test substance:

Remarks:

Quino(2,3-b)acridine-7,14-dione,5,12-dihydro-2, 9 dimethyl Estimation Level III Fugacity Model; EPIWIN: EQC from Syracuse Research Corporation

Distribution (%) Air

1.56 E-006

Water

15

Soil

84.8

Sediment

.122 Since no experimental values were available the physical chemical

Method Test type:

Model used:

Remarks:

Results Model data and results:

Estimated distribution and media concentration (levels II/III):

Remarks:

values utilized in this model were default parameters from within EPIWIN. Meylan, W. (1993). User's Guide for the Estimation Programs Interface (EPI), Version 3.10, Syracuse Research Corporation, Syracuse, New York 13210. The Level III model incorporated into EPIWIN is a Syracuse Research Corporation adaptation of the methodology described by Mackay *et al.* 1996; *Environ. Toxicol. Chem.* **15**(9), 1618-1626 and 1627-1637.

Conclusions

References

Other

D3. Transport between Environmental Compartments (Fugacity)	Quino(2,3-b)acridine-7,14-dione,5, 6, 12, 13-tetrahydro	EstimationLevel III
Test Substance	Fugacity Model; EPIWIN:EQC from Syracuse Research Corporation	
Test	Distribution (%)	Air
substance:	Water	10.8
Remarks:	86.1	Sediment
Method	Test type:	3.08
	Model used:	Since no experimental values were available the physical chemical values utilized in this model were default parameters from within EPIWIN.
	Remarks:	Meylan, W. (1993). User's Guide for the Estimation Programs Interface (EPI), Version 3.10, Syracuse Research Corporation, Syracuse, New York 13210. The Level III model incorporated into EPIWIN is a Syracuse Research Corporation adaptation of the methodology described by Mackay <i>et al.</i> 1996; <i>Environ. Toxicol. Chem.</i> 15 (9), 1618-1626 and 1627-1637.
Results	Model data and results:	
	Estimated distribution and media concentration (levels II/III):	
	Remarks:	
Conclusions		
References		
Other		

IV. Ecotoxicity

A. Acute Toxicity to Fish

Test Substance Quino(2,3-b)acridine-7,14-dione,5,12-dihydro

Test substance:

Remarks:

Method

Method: Estimation

Test type:

GLP:

Year:

Species/strain: Fish

Analytical monitoring:

Exposure period:

Remarks:

Results

Nominal concentration:

Measured concentration:

Endpoint value: LC50 96 Hours 885 mg/L , 14 Day LC 50 1454 mg/L

Biological observations:

Statistical methods:

Remarks:

Conclusions

Due to its insolubility, the material is not anticipated to be toxic in the water at saturation.

Data Quality

Reliability:

Remarks:

References

EPI Suite ECOSAR v .099 Syracuse Research Corporation, Syracuse, New York, Anliker R. and Moser P. , The Limits of Bioaccumulation of Organic

Other

Pigments in Fish: Their Relation to the Partition Coefficient and the Solubility in Water and Octanol, Ecotox. And Envir. Saf. 13, Pp. 43-52 (1987)

A2. Acute Toxicity to Fish

Test Substance

Test substance: Quino(2,3-b)acridine-7,14-dione,5,12-dihydro-2,9-dimethyl

Remarks:

Method

Estimation

Method:

Test type:

GLP:

Year:

Fish

Species/strain:

Analytical monitoring:

Exposure period:

Remarks:

Results

Nominal concentration:

Measured concentration:

LC50 96 Hours 91 mg/L , 14 Day LC 50, 178.04 mg/L

Endpoint value:

Biological observations:

Statistical methods:

Remarks:

Conclusions

Due to its insolubility, the material is not anticipated to be toxic in the water at saturation.

Data Quality

Reliability:

Remarks:

References

EPI Suite ECOSAR v .099 Syracuse Research Corporation, Syracuse, New York, Anliker R. and Moser P. , The Limits of Bioaccumulation of Organic Pigments in Fish: Their Relation to the Partition Coefficient and the Solubility in Water and Octanol, Ecotox. And Envir. Saf. 13, Pp. 43-52 (1987)

Other

B. Acute Toxicity to
Test substance:

Remarks:

Quino(2,3-b)acridine-7,14-dione,5,12-dihydro-2,9-dimethyl

Method

Method:

Test type:

GLP:

Year:

Species/strain:

OECD 211 Daphnia Magna reproduction

Analytical monitoring:

Exposure period:

Yes

Remarks:

Daphnia Magna

Results

Nominal concentration:

Measured concentration:

Endpoint value:

Reproduction

Biological observations:

Statistical methods:

No differences in the onset of brood production observed in the concentration group in comparison to the control. The reproduction rate in the concentration group showed no statistically significant changes in comparison to the control.

Remarks:

Conclusions

Data Quality

Reliability:

Remarks:

References

Reliable without restriction

Other

Company sponsored data

C. Toxicity to Aquatic Plants

Test Substance

Test substance: Quino(2,3-b)acridine-7,14-dione,5,12-dihydro

Remarks:

Method

Method: Estimation

Test type:

GLP:

Year:

Species/strain: Algae

Endpoint basis:

Exposure period:

Analytical procedures:

Remarks:

Results

Nominal concentration:

Measured

concentration:

Endpoint value:

NOEC:

Biological

observations:

Was control response

satisfactory:

Statistical Methods:

Remarks:

The conduction of an algae test with C.I. Pigment Violet 19, Red 122 or dyhydroquinacridone is problematic as the substance leads to a strong coloring of the test solution and therefore to a reduction of light intensity. Therefore, the assessment is made on the basis of computer model estimation.

96 hour EC-50, 548.6

Conclusions

Data Quality

Reliability:

Remarks:

References

reliable with restriction

Other

EPI Suite ECOSAR v .099 Syracuse Research Corporation, Syracuse, New York,

V. Toxicological Data

A. Acute Toxicity Test Substance

Test substance: Quino(2,3-b)acridine-7,14-dione,5,12-dihydro
Purity was unknown

Remarks:

Method

Method: Acute lethality; Other
Test type: LD₅₀ estimate
GLP: No (Pre-GLP)
Year: 1957
Species/strain: Male albino Rats
Route of exposure: Oral gavage
Dose levels: 1000, 3400, 5000, 7500 mg/kg
Remarks:

Results

Value: LD₅₀ = >7,500 mg/kg.
Deaths at each dose:
Remarks: All rats survived, Clinically, the rats showed only mild discomfort at the higher levels. The material appeared to be excreted in the feces.

Conclusions

Material would be considered as not toxic.

Data Quality

Reliability: Reliable with restrictions
Remarks: The study was conducted quite some time ago and hence many study details are missing from the report and not available. However, basic data are given and results are consistent with other data for pigments of this type.

References

Haskwll Laboratory, Medical Research project, No., MR-166, See also, Mone J.G. 1968, Federation Series on Coating Technology, Unit 9 Organic Pigments, Federation of Societies for Paint Technology, Philadelphia, PA 19107.

Other

Acute toxicity

Test substance:

Quino(2,3-b)acridine-7,14-dione,5,12-dihydro-2,9-dimethyl

Remarks:

Purity was unknown

Method

Method: Acute lethality; Other
Test type: LD₅₀ estimate
GLP: No (Pre-GLP)
Year: 1968
Species/strain: Rat and mouse
Route of exposure: Oral gavage
Dose levels: Unknown
Remarks:

Results

Value: LD₅₀ = >5,000 mg/kg.
Deaths at each dose:
Remarks:

Conclusions

Material would be considered as not toxic.

Data Quality

Reliability: Reliable with restrictions
Remarks:

References

Mone J.G. 1968, Federation Series on Coating Technology, Unit 9 Organic Pigments, Federation of Societies for Paint Technology, Philadelphia, PA 19107.

Other

A. Acute Toxicity

Test Substance

Test substance: Quino(2,3-b)acridine-7,14-dione,5,12-dihydro
Purity was unknown

Remarks:

Method

Method: Acute lethality; Other
Test type: LC₅₀ estimate
GLP: No (Pre-GLP)
Year: 1983
Species/strain: Male CRL:CD® Rats
Route of exposure: Inhalation
Dose levels: 1.5, 1.6, 2.4, 2.6 and 3.1 mg/l
Remarks:

Results

Value: LC₅₀ = >3.1 mg/L
Deaths at each dose:
Remarks: All rats survived, Groups of 6 rats were used at each dose up to 3.1 mg/L.
Other than transient weight losses there were no significant clinical signs of toxicity observed.

Conclusions

Material would be considered as not toxic.

Data Quality

Reliability: Reliable with restrictions
Remarks: The study is well documented and followed accepted protocols.

References

Haskell Laboratory, Medical Research Report Number 746-82, Project, No.,
MR-4368-001,

Other

Repeated Dose Toxicity Test**Substance**

Test substance: Quino(2,3-b)acridine-7,14-dione,5,12-dihydro
Remarks:

Method

Method: Repeated subchronic dose
Test type:
GLP: NA
Year: 1982
Species/strain: Fisher 344 Rats
Route of exposure: Gavage
Duration of test: 33 days
Exposure levels: Rats 0. 1.0%, 5.0 %,10.0% in the diet

Sex:

Exposure period: 33 days
Post-exposure
Observation period:
Remarks:

Results

NOAEL (NOEL): Up to 10 % of the diet
After repeated oral administration for 33 days in rats, pigment Violet 19 showed no signs of toxicity. None of the study animals died on test. Clinically, high dose (10%) animals demonstrated significant body weight gain compared to controls, which appeared to be associated with corresponding increase in food intake. It appeared that these animals tried to compensate by overeating for the decrease in nutritional intake in the 10% pigment diet. These animals, and to a lesser extent the 5% and 1% dose level animals, also had purple tinged fur, apparently as a result from coming in contact with the color pigment in feed hoppers. No other clinical sign were seen in the animals. Clinical pathology, ophthalmology, cytogenetic analysis, organ weights, and gross and tissue morphology examinations failed to detect the toxicity associated with Pigment Violet 19. (A very slight but statistically significant increase in methemoglobin levels was seen for the high dose female rats at week 2, but in neither sex at week 4. Not considered related to Pigment Violet 19 treatment.) In general, under the conditions of the study, toxicity was not observed following the administration of up to 10% Pigment Violet 19 in the diet of Fisher 344 rats for 33 days.

Conclusions

Test substance is not toxic

Data Quality

Reliability: Reliable without restriction
Remarks:

References:

Microbiological Associates, September, 1988 Study for CTFA,
CTFA 86-MAI-A; MAG1003-T03022, Subchronic Oral Toxicity In Rats.

Other

Repeated Dose Toxicity Test**Substance**

Test substance: Quino(2,3-b)acridine-7,14-dione,5,12-dihydro

Remarks:

Method

Method: Absorption/ Distribution/Excretion

Test type:

GLP: NA

Year: 1991

Species/strain: Fisher 344 Rats

Route of exposure: Gavage

Duration of test: 72 Hours

Exposure levels: 3.22 mg/kg and 33.68 uCi/kg Males, 5.44mg/kg 56.81 uCi/kg Females

Sex:

Exposure period: single dose

Post-exposure 72 hour follow up

Observation period:

Remarks:

Results

NOAEL (NOEL): N/A

The test article was administered as a suspension in aqueous 1% carboxymethyl cellulose at a concentration of .3905 mg QV19 and the same amount was administered to each rat. Urine and feces were collected from each rat at 2,8,24,48 and 72 hours after dosing; cage washes and gastrointestinal tract of each rat were removed after euthanasia at 72 hour post-dose. Recovery of administered radioactive dose was virtually complete. 91.9+ or - 6.9 % of dose males; 100.5+ or - 8.7% of dose females. There were no gender related differences in the route of excretion. More than 90 % of the recovered radioactivity was eliminated in the feces and cage washes, which appeared to contain residual fecal matter. At 72 hours virtually all radioactivity had been eliminated by the rats. The urine from both groups of rats contained very low amounts of radioactivity. 0.0089% of dose males; 0.0020% of dose females.

Conclusions

Radioactivity from a single oral dose of Pigment Violet 19 given to male and female rats was eliminated almost completely in the feces.

Data Quality

Reliability:

Reliable without restriction

Remarks:

References:

Bio-Research 1991, Study done for CTFA,

Other

**Repeated Dose Toxicity Test
Substance**

Test substance: Quino(2,3-b)acridine-7,14-dione,5,12-dihydro
Remarks:

Method

Method: Whole Body Radiography
Test type:
GLP: NA
Year: 1991
Species/strain: Fisher 344 Rats
Route of exposure: Gavage
Duration of test: 48 Hours
Exposure levels:

Sex: single dose
Exposure period: 48 hour follow up
Post-exposure
Observation period:
Remarks:

Results

NOAEL (NOEL): N/A
Groups of male and female Fisher 344 rats were administered orally by gavage pigment violet 19 and radioactive trace material. And the tissue distribution of radioactivity determined by whole body autoradiography at selected times up to 48 hours after dosing. The autoradiogram showed that radioactivity was localized only in the gastrointestinal tract of both male and female rats. No radioactivity was detected in other organs and tissues of the animals. The highest concentrations of radioactivity were found at 2 hours post dosing . Most of the radioactivity was eliminated from the rats at 24 hours and it was virtually undetected at 18 hours post-dose.

Conclusions

Whole body autoradiography indicated that virtually no radioactivity was detected in tissues, supporting the previous finding that, radioactivity from a single oral dose of Pigment Violet 19 given to male and female rats was eliminated almost completely in the feces.

Data Quality

Reliability: Reliable without restriction
Remarks:

References:

Bio-Research 1991, Study done for CTFA,

Other

C. Genetic Toxicity - Mutation

Test Substance

Test substances: Quino(2,3-b)acridine-7,14-dione,5,12-dihydro

Remarks:

Method

Method: In Vitro Mutagenicity\
Test type: Ames
GLP:
Year: 1975
Species/strain: Salmonella typhimurium
Metabolic activation: Yes,
Concentration tested: 100 ug per plate
Remarks:

Results

Result: Negative
Cytotoxic
concentration:
Precipitation
concentration:
Genotoxic effects
With activation: Negative
Without activation: Negative
Statistical methods:
Remarks:

Conclusions

Data Quality

Reliability: Reliable without restrictions
Remarks: Six crystal forms of Violet 19 were tested, No mutagenic response was seen with any of the pigments tested.

References

Salmonella/ Mammalian- microsome plats incorporation mutagenicity/Haskell
Laboratory Report No. 558-75, See also CTFA Report, Quinacridone Violet
19

C. Genetic Toxicity - Mutation

Test substance: Quino(2,3-b)acridine-7,14-dione,5,12-dihydro-2,9-dimethyl
Remarks:

Method

Method: OECD 471
Test type: Ames
GLP:
Year: 2000
Species/strain: Salmonella typhimurium
Metabolic activation: With and without
Concentration tested: 5000 ug/plate with and without activation
Remarks:

Results

Result: Negative in all bacterial strains with and without activation
Cytotoxic concentration:
Precipitation concentration:
Genotoxic effects
 With activation: Negative
 Without activation: Negative
Statistical methods:
Remarks:

Conclusions

Data Quality

Reliability: Reliable without restriction Remarks:

References

Notox Project No. 289845

Other

D. Genetic Toxicity – Chromosomal Aberrations

Test Substance

Test substance: Quino(2,3-b)acridine-7,14-dione,5,12-dihydro

Remarks:

Method

Method: OECD 473
Test type: Cytogenetics Assay
GLP:
Year: 2001
Species/strain: Mouse Lymphoma L5178Y Cells
Exposure period:
Remarks:

Results

Result: Negative
Genotoxic effects: Negative
Concentration tested
Statistical methods:
Remarks:
Not mutagenic

Conclusions**Data Quality**

Reliability: Reliable without restriction
Remarks:

References

CTFA Micronucleus in vivo and mouse lymphoma cell mutation
underway January, 2000

Other**E. Developmental Toxicity**

Test Substance

See subchronic toxicity and absorption studies above.

Test substance:

Remarks:

Method

Method:

GLP:

Year:

Species/strain:

Sex:

Route of exposure:

Exposure levels:

Actual doses received:

Exposure period:

Duration of test:

Remarks:

Results

Maternal toxicity

NOEL:

NOEL for

teratogenicity:

NOEL for fetotoxicity:

Parental toxic

responses:

Fetal toxic responses

dose:

Statistical Methods:

Remarks:

Since available radiographic studies establish consistently no significant uptake or absorption from this substance, no further reproduction or developmental studies are planned.

Conclusions**Data Quality**

Reliability:

Remarks:

References**Other**

F. Toxicity to Reproduction

Test Substance

Test substance:

Remarks:

Method

Method:

GLP:

Year:

Species/strain:Sex:

Route of exposure:

Exposure levels:

Exposure period:

Duration of test:

Remarks:

Results

Maternal toxicity NOEL:

Parental toxic responses:

Fetal toxic responses dose:

Statistical Methods:

Remarks:

Conclusions

Data Quality

Reliability:

Remarks:

References

Other

Test substance: (1) Quino(2,3-b)acridine-7,14-dione,5,12-dihydro and (2) Quino(2,3-b)acridine-7,14-dione,5,12-dihydro-2,9-dimethyl

Remarks:

Method

Method: Irritation to the rabbit eye
Test type: eye irritation
GLP: unknown
Year: (1)1982 / (2)1992
Species/strain: rabbitt
Route of exposure:
Dose levels:
Remarks:

Results

Value: negative
Deaths at each dose:
Remarks:

Conclusions Non-irritating

Data Quality

Reliability: unassignable
Remarks:

References (1) Dupont Haskell Report HLO 397-83\
Research Labs Project No. MB 92-1750D

(2) MB

Other

Acute toxicity

Test substance: (1) Quino(2,3-b)acridine-7,14-dione,5,12-dihydro and (2) Quino(2,3-b)acridine-7,14-dione,5,12-dihydro-2,9-dimethyl

Remarks:

Method

Method: Skin irritation to the rabbit
Test type: Skin irritation
GLP: unknown
Year: (1)1992 (2) 1982
Species/strain: rabbitt
Route of exposure:
Dose levels:
Remarks:

Results

Value: negative
Deaths at each dose:
Remarks:

Conclusions

Data Quality

Reliability: unassignable
Remarks:

References

(1) Dupont Haskell Report HLO 584-82
(2) MB Research Labs Project No. MB 92-1750CD

Other

I. General Information

CAS Number: C.I. Pigment Violet 19, (CAS No. 1047-16-1)

Name: Quino(2,3-b)acridine-7,14-dione,5,12-dihydro

CAS Number: C.I. Pigment Violet 122, (CAS No. 980-26-7)

Name: Quino(2,3-b)acridine-7,14-dione,5,12-dihydro-2,9-dimethyl

CAS Number: (CAS NO. 5862-38-4)

Name: Dihydro Quinacridone

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II. Physical-Chemical Data**A1. Melting Point****Test Substance**

Test substance: Quino(2,3-b)acridine-7,14-dione,5,12-dihydro

Remarks:

Method

Method: Measured

Remarks:

Results

Melting point value: >400 °C

Remarks:

References**Other**

Anliker R. and Moser P. , The Limits of Bioaccumulation of Organic Pigments in Fish: Their Relation to the Partition Coefficient and the Solubility in Water and Octanol, Ecotox. And Envir. Saf. 13, Pp. 43-52 (1987) Data is consistent with melting points for the class of pigments and other available measurements,

A2. Melting Point

Test Substance

Test substance: Quino(2,3-b)acridine-7,14-dione,5,12-dihydro-2,9-dimethyl

Remarks:

Method

Method: Adapted Joback Method

Remarks:

Results

Melting point value: 349 °C

Remarks:

References

EPIWIN v 3.10, Syracuse Research Corporation, Syracuse, New York

Other

Data is consistent with melting points for the class of pigments and other available measurements.

A2. Melting Point

Test Substance

Test substance: Dihydro Quinacridone

Remarks:

Method

Method: Esitimate, Adapted Joback method

Remarks:

Results

Melting point value: 349.84 °C

Remarks:

References

EPIWIN v 3.10, Syracuse Research Corporation, Syracuse, New York

Other

Data is consistent with melting points for the class of pigments and other available measurements.

B. Boiling Point
Test Substance
Test substance: SOLID N/A
Remarks:

Method
Method:
Remarks:

Results
Boiling point value:
Remarks:

References

Other

C1. Vapor Pressure
Test Substance
Test substance: Quino(2,3-b)acridine-7,14-dione,5,12-dihydro
Remarks:

Method
Method: Estimation
Remarks: Modified Grain method

Results
Vapor pressure value: 1.13 E-010 mmHg
Temperature:
Remarks:

References
MPBPWIN v1.40 in EPIWIN v 3.10, Syracuse Research Corporation,
Syracuse, New York

Other

C2. Vapor Pressure
Test Substance
Quino(2,3-b)acridine-7,14-dione,5,12-dihydro-2,9-dimethyl

Remarks:

Results
Vapor pressure value: 2.14 E-011 mm Hg
Temperature:

Remarks:

Method

Method:
Remark:

Estimation
Modified Grain method

References
York

MPBPWIN v 1.40 in EPIWIN v 3.10, Syracuse Research Corporation, Syracuse, New York

Other

D. Partition Coefficient**Test Substance**

Test substance: Quino(2,3-b)acridine-7,14-dione,5,12-dihydro

Remarks:

Method

Method: Octanol Solubility Determination
Remarks: GLP \1996\ Guideline 40 CFR 796

Results

Solubility: .808 mg/L at 20 °C
Remarks:

References

Corning Hazleton, CHW 6623-105, 1996, Log Kow partition coefficient cannot be determined for this compound, solubility in water and octanol are too low to produce a meaningful value.

Other**E. Water Solubility****Test Substance**

Test substance: Quino(2,3-b)acridine-7,14-dione,5,12-dihydro

Remarks:

Method

Method: Estimated
Remarks:

Results

Value: <.808 mg/L
Temperature: 20 °C
Description:
Remarks: Extremely Low Solubility

References

Corning Hazleton, CHW 6623-105, 1996, Log Kow partition coefficient cannot be determined for this compound, solubility in water and octanol are too low to produce a meaningful value.

Other

III. Environmental Fate Endpoints

A. Photodegradation

Test Substance

Test substance: Quino(2,3-b)acridine-7,14-dione,5,12-dihydro

Remarks:

Method

Method: Estimate

Test type: Water\sunlight

Remarks:

Results

Temperature:

Degradation Rate

: Half-life .642 hours

Ozone reaction:

Remarks:

Conclusions

[Estimate only applies to minute soluble fraction]

References

AOPWIN v 1.91, Syracuse Research Corporation, Syracuse, New York

Other

A2. Photodegradation

Test substance: Quino(2,3-b)acridine-7,14-dione,5,12-dihydro-2,9-dimethyl

Remarks:

Method

Method: Estimate
Test type: Water\sunlight
Remarks:

Results

Temperature:
Hydroxyl radicals reaction
OH Rate constant:
Half-life .641 hours
Ozone reaction:
Remarks:

Conclusions [Estimate only applies to minute soluble fraction]

References AOPWIN v 1.91, Syracuse Research Corporation, Syracuse, New York

Other

B. Stability in Water**Test Substance**

Test substance: Quino(2,3-b)acridine-7,14-dione,5,12-dihydro

Remarks:

Method

Method:

Test type:

GLP:

Remarks:

Results

Half-life:

Percent hydrolyzed in
5 days (120 hs)

at 50 °C :

Remarks:

Conclusions**Data Quality**

Remarks:

References**Other**

Due to extremely low solubility, hydrolysis in water for quinacridone pigments cannot be estimated or measured accurately at this time. See HYDROWIN v 1.67 Syracuse Research Corporation, Syracuse, New York

C. Biodegradation

Test Substance

Test substance: Quino(2,3-b)acridine-7,14-dione,5,12-dihydro

Remarks:

Method

Method: Estimation

Test type:

GLP:

Year:

Remarks:

Results

Results: noreadily biodegradable

Remarks:

Conclusions

Results apply to all three quinacridone pigments.

Data Quality

Remarks:

References

EPI Suite HYDROWIN v 4.02 Syracuse Research Corporation, Syracuse, New York, Anliker R., and Clarke, E.A. Ecology and Toxicology of Synthetic Organic Pigments, Chemosphere, Vol. 9, pp. 595-609 (1980)

Other

D. Transport between Environmental Compartments (Fugacity)

Test Substance

Test substance: Quino(2,3-b)acridine-7,14-dione,5,12-dihydro
Remarks:

Method

Test type: Estimation
Model used: Level III Fugacity Model; EPIWIN:EQC from Syracuse Research Corporation
Remarks:

Results

Model data and results:	Distribution (%)
Air	5.15 E-007
Water	37.1
Soil	62.8
Sediment	.0897

Remarks:

Conclusions

Since no experimental values were available the physical chemical values utilized in this model were default parameters from within EPIWIN.

References

Meylan, W. (1993). User's Guide for the Estimation Programs Interface (EPI), Version 3.10, Syracuse Research Corporation, Syracuse, New York 13210. The Level III model incorporated into EPIWIN is a Syracuse Research Corporation adaptation of the methodology described by Mackay *et al.* 1996; *Environ. Toxicol. Chem.* **15**(9), 1618-1626 and 1627-1637.

Other

D2. Transport between Environmental Compartments (Fugacity)Test Substance

Test substance:	Distribution (%)	Air	Water	Soil
Remarks:	84.8	15	Sediment	1.56 E-006

Method Test type:

Model used:

Remarks:

Results

Model data and results: Quino(2,3-b)acridine-7,14-dione,5,12-dihydro-2, 9 dimethyl Estimation Level III Fugacity Model; EPIWIN: EQC from Syracuse Research Corporation
Estimated distribution and media concentration (levels II/III):
Remarks:

Conclusions

References

Other

D3. Transport between Environmental Compartments (Fugacity)
 Test Substance Test
 substance: Remarks:

Quino(2,3-b)acridine-7,14-dione,5, 6, 12, 13-tetrahydroEstimationLevel III
 Fugacity Model; EPIWIN:EQC from Syracuse Research Corporation
 Distribution (%) Air 1.04 E-009
 Water 10.8
 86.1 Sediment Soil

Method Test type:
 Model used:
 Remarks:

3.08Since no experimental values were available the physical chemical
 values utilized in this model were default parameters from within
 EPIWIN.Meylan, W. (1993). User's Guide for the Estimation Programs
 Interface (EPI), Version 3.10, Syracuse Research Corporation, Syracuse, New
 York 13210. The Level III model incorporated into EPIWIN is a Syracuse
 Research Corporation adaptation of the methodology described by Mackay *et*
al. 1996; *Environ. Toxicol. Chem.* **15(9)**, 1618-1626 and 1627-1637.

Results Model data and results:
 Estimated distribution
 and media concentration
 (levels II/III):
 Remarks:

Conclusions

References

Other

IV. Ecotoxicity

A. Acute Toxicity to Fish

Test Substance

Test substance:

Remarks:

Quino(2,3-b)acridine-7,14-dione,5,12-dihydro

Method

Method:

Test type:

GLP:

Year:

Species/strain:

Analytical monitoring:

Exposure period:

Remarks:

Estimation

Fish

Results

Nominal concentration:

Measured concentration:

Endpoint value:

Biological observations:

LC50 96 Hours 885 mg/L , 14 Day LC 50 1454 mg/L

Statistical methods:

Remarks:

Conclusions

Due to its insolubility, the material is not anticipated to be toxic in the water at saturation.

Data Quality

Reliability:

Remarks:

References

EPI Suite ECOSAR v .099 Syracuse Research Corporation, Syracuse, New York, Anliker R. and Moser P. , The Limits of Bioaccumulation of Organic

Other

Pigments in Fish: Their Relation to the Partition Coefficient and the Solubility in Water and Octanol, Ecotox. And Envir. Saf. 13, Pp. 43-52 (1987)

A2. Acute Toxicity to Fish

Test Substance

Test substance: Quino(2,3-b)acridine-7,14-dione,5,12-dihydro-2,9-dimethyl

Remarks:

Method

Estimation

Method:

Test type:

GLP:

Year:

Fish

Species/strain:

Analytical monitoring:

Exposure period:

Remarks:

Results

Nominal concentration:

Measured concentration:

LC50 96 Hours 91 mg/L , 14 Day LC 50, 178.04 mg/L

Endpoint value:

Biological observations:

Statistical methods:

Remarks:

Conclusions

Due to its insolubility, the material is not anticipated to be toxic in the water at saturation.

Data Quality

Reliability:

Remarks:

References

EPI Suite ECOSAR v .099 Syracuse Research Corporation, Syracuse, New York, Anliker R. and Moser P. , The Limits of Bioaccumulation of Organic Pigments in Fish: Their Relation to the Partition Coefficient and the Solubility in Water and Octanol, Ecotox. And Envir. Saf. 13, Pp. 43-52 (1987)

Other

B. Acute Toxicity to
Test substance:

Remarks:

Quino(2,3-b)acridine-7,14-dione,5,12-dihydro-2,9-dimethyl

Method

Method:

Test type:

GLP:

Year:

Species/strain:

OECD 211 Daphnia Magna reproduction

Analytical monitoring:

Exposure period:

Yes

Remarks:

Daphnia Magna

Results

Nominal concentration:

Measured concentration:

Endpoint value:

Reproduction

Biological observations:

Statistical methods: No differences in the onset of brood production observed in the concentration group in comparison to the control. The reproduction rate in the concentration group showed no statistically significant changes in comparison to the control.

Remarks:

Conclusions

Data Quality

Reliability:

Remarks:

References

Reliable without restriction

Other

Company sponsored data

C. Toxicity to Aquatic Plants

Test Substance

Test substance: Quino(2,3-b)acridine-7,14-dione,5,12-dihydro

Remarks:

Method

Method: Estimation

Test type:

GLP:

Year:

Species/strain: Algae

Endpoint basis:

Exposure period:

Analytical procedures:

Remarks:

Results

Nominal concentration:

Measured

concentration:

Endpoint value:

NOEC:

Biological

observations:

Was control response

satisfactory:

Statistical Methods:

Remarks:

The conduction of an algae test with C.I. Pigment Violet 19, Red 122 or dyhydroquinacridone is problematic as the substance leads to a strong coloring of the test solution and therefore to a reduction of light intensity. Therefore, the assessment is made on the basis of computer model estimation.

96 hour EC-50, 548.6

Conclusions

Data Quality

Reliability:

Remarks:

References

reliable with restriction

Other

EPI Suite ECOSAR v .099 Syracuse Research Corporation, Syracuse, New York,

V. Toxicological Data

A. Acute Toxicity

Test Substance

Test substance: Quino(2,3-b)acridine-7,14-dione,5,12-dihydro
Purity was unknown

Remarks:

Method

Method: Acute lethality; Other
Test type: LD₅₀ estimate
GLP: No (Pre-GLP)
Year: 1957
Species/strain: Male albino Rats
Route of exposure: Oral gavage
Dose levels: 1000, 3400, 5000, 7500 mg/kg
Remarks:

Results

Value: LD₅₀ = >7,500 mg/kg.
Deaths at each dose:
Remarks: All rats survived, Clinically, the rats showed only mild discomfort at the higher levels. The material appeared to be excreted in the feces.

Conclusions

Material would be considered as not toxic.

Data Quality

Reliability: Reliable with restrictions
Remarks: The study was conducted quite some time ago and hence many study details are missing from the report and not available. However, basic data are given and results are consistent with other data for pigments of this type.

References

Haskwll Laboratory, Medical Research project, No., MR-166, See also, Mone J.G. 1968, Federation Series on Coating Technology, Unit 9 Organic Pigments, Federation of Societies for Paint Technology, Philadelphia, PA 19107.

Other

Acute toxicity

Test substance: Quino(2,3-b)acridine-7,14-dione,5,12-dihydro-2,9-dimethyl

Remarks: Purity was unknown

Method

Method: Acute lethality; Other
Test type: LD₅₀ estimate
GLP: No (Pre-GLP)
Year: 1968
Species/strain: Rat and mouse
Route of exposure: Oral gavage
Dose levels: Unknown
Remarks:

Results

Value: LD₅₀ = >5,000 mg/kg.
Deaths at each dose:
Remarks:

Conclusions

Material would be considered as not toxic.

Data Quality

Reliability: Reliable with restrictions
Remarks:

References

Mone J.G. 1968, Federation Series on Coating Technology, Unit 9 Organic Pigments, Federation of Societies for Paint Technology, Philadelphia, PA 19107.

Other

A. Acute Toxicity

Test Substance

Test substance: Quino(2,3-b)acridine-7,14-dione,5,12-dihydro
Purity was unknown

Remarks:

Method

Method: Acute lethality; Other
Test type: LC₅₀ estimate
GLP: No (Pre-GLP)
Year: 1983
Species/strain: Male CRL:CD® Rats
Route of exposure: Inhalation
Dose levels: 1.5, 1.6, 2.4, 2.6 and 3.1 mg/l
Remarks:

Results

Value: LC₅₀ = >3.1 mg/L
Deaths at each dose:
Remarks: All rats survived, Groups of 6 rats were used at each dose up to 3.1 mg/L. Other than transient weight losses there were no significant clinical signs of toxicity observed.

Conclusions

Material would be considered as not toxic.

Data Quality

Reliability: Reliable with restrictions
Remarks: The study is well documented and followed accepted protocols.

References

Haskell Laboratory, Medical Research Report Number 746-82, Project, No., MR-4368-001,

Other

Repeated Dose Toxicity Test**Substance**

Test substance: Quino(2,3-b)acridine-7,14-dione,5,12-dihydro
Remarks:

Method

Method: Repeated subchronic dose
Test type:
GLP: NA
Year: 1982
Species/strain: Fisher 344 Rats
Route of exposure: Gavage
Duration of test: 33 days
Exposure levels: Rats 0. 1.0%, 5.0 %,10.0% in the diet

Sex:

Exposure period: 33 days
Post-exposure
Observation period:
Remarks:

Results

NOAEL (NOEL): Up to 10 % of the diet
After repeated oral administration for 33 days in rats, pigment Violet 19 showed no signs of toxicity. None of the study animals died on test. Clinically, high dose (10%) animals demonstrated significant body weight gain compared to controls, which appeared to be associated with corresponding increase in food intake. It appeared that these animals tried to compensate by overeating for the decrease in nutritional intake in the 10% pigment diet. These animals, and to a lesser extent the 5% and 1% dose level animals, also had purple tinged fur, apparently as a result from coming in contact with the color pigment in feed hoppers. No other clinical sign were seen in the animals. Clinical pathology, ophthalmology, cytogenetic analysis, organ weights, and gross and tissue morphology examinations failed to detect the toxicity associated with Pigment Violet 19. (A very slight but statistically significant increase in methemoglobin levels was seen for the high dose female rats at week 2, but in neither sex at week 4. Not considered related to Pigment Violet 19 treatment.) In general, under the conditions of the study, toxicity was not observed following the administration of up to 10% Pigment Violet 19 in the diet of Fisher 344 rats for 33 days.

Conclusions

Test substance is not toxic

Data Quality

Reliability: Reliable without restriction
Remarks:

References:

Microbiological Associates, September, 1988 Study for CTFA,
CTFA 86-MAI-A; MAG1003-T03022, Subchronic Oral Toxicity In Rats.

Other

Repeated Dose Toxicity Test**Substance**

Test substance: Quino(2,3-b)acridine-7,14-dione,5,12-dihydro
Remarks:

Method

Method: Absorption/ Distribution/Excretion
Test type:
GLP: NA
Year: 1991
Species/strain: Fisher 344 Rats
Route of exposure: Gavage
Duration of test: 72 Hours
Exposure levels: 3.22 mg/kg and 33.68 uCi/kg Males, 5.44mg/kg 56.81 uCi/kg Females

Sex:

Exposure period: single dose
Post-exposure 72 hour follow up
Observation period:
Remarks:

Results

NOAEL (NOEL): N/A
The test article was administered as a suspension in aqueous 1% carboxymethyl cellulose at a concentration of .3905 mg QV19 and the same amount was administered to each rat Urine and feces were collected from each rat at 2,8,24,48 and 72 hours after dosing; cage washes and gastrointestinal tract of each rat were removed after euthanasia at 72 hour post-dose. Recovery of administered radioactive dose was virtually complete.91.9+ or - 6.9 % of dose males; 100.5+ or _8.7% of dose females. There were no gender related differences in the route of excretion. More than 90 % of the recovered radioactivity was eliminated in the feces and cage washes, which appeared to contain residual fecal matter. At 72 hours virtually all radioactivity had been eliminated by the rats. The urine from both groups of rats contained very low amounts of radioactivity.0089% of dose males;.0020% of dose females.

Conclusions

Radioactivity from a single oral dose of Pigment Violet 19 given to male and female rats was eliminated almost completely in the feces.

Data Quality

Reliability: Reliable without restriction
Remarks:

References:

Bio-Research 1991, Study done for CTFA,

Other

**Repeated Dose Toxicity Test
Substance**

Test substance: Quino(2,3-b)acridine-7,14-dione,5,12-dihydro
Remarks:

Method

Method: Whole Body Radiography
Test type:
GLP: NA
Year: 1991
Species/strain: Fisher 344 Rats
Route of exposure: Gavage
Duration of test: 48 Hours
Exposure levels: ??

Sex:

Exposure period: single dose
Post-exposure 48 hour follow up
Observation period:
Remarks:

Results

NOAEL (NOEL): N/A
Groups of male and female Fisher 344 rats were administered orally by gavage pigment violet 19 and radioactive trace material. And the tissue distribution of radioactivity determined by whole body autoradiography at selected times up to 48 hours after dosing. The autoradiogram showed that radioactivity was localized only in the gastrointestinal tract of both male and female rats. No radioactivity was detected in other organs and tissues of the animals. The highest concentrations of radioactivity were found at 2 hours post dosing . Most of the radioactivity was eliminated from the rats at 24 hours and it was virtually undetected at 18 hours post-dose.

Conclusions

Whole body autoradiography indicated that virtually no radioactivity was detected in tissues, supporting the previous finding that, radioactivity from a single oral dose of Pigment Violet 19 given to male and female rats was eliminated almost completely in the feces.

Data Quality

Reliability: Reliable without restriction
Remarks:

References:

Bio-Research 1991, Study done for CTFA,

Other

C. Genetic Toxicity - Mutation

Test Substance

Test substances: Quino(2,3-b)acridine-7,14-dione,5,12-dihydro

Remarks:

Method

Method: In Vitro Mutagenicity\
Test type: Ames
GLP: ??
Year: 1975
Species/strain: Salmonella typhimurium
Metabolic activation: Yes,
Concentration tested: 100 ug per plate
Remarks:

Results

Result: Negative
Cytotoxic
concentration:
Precipitation
concentration:
Genotoxic effects
With activation: Negative
Without activation: Negative
Statistical methods:
Remarks:

Conclusions

Data Quality

Reliability: Reliable without restrictions
Remarks: Six crystal forms of Violet 19 were tested, No mutagenic response was seen with any of the pigments tested.

References

Salmonella/ Mammalian- microsome plats incorporation mutagenicity/Haskell
Laboratory Report No. 558-75, See also CTFA Report, Quinacridone Violet
19

C. Genetic Toxicity - Mutation

Test substance: Quino(2,3-b)acridine-7,14-dione,5,12-dihydro-2,9-dimethyl
Remarks:

Method

Method: OECD 471
Test type: Ames
GLP: ??
Year: 2000
Species/strain: Salmonella typhimurium
Metabolic activation: With and without
Concentration tested: ??5000 ug/plate with and without activation
Remarks:

Results

Result: Negative in all bacterial strains with and without activation
Cytotoxic concentration:
Precipitation concentration:
Genotoxic effects
 With activation: Negative
 Without activation: Negative
Statistical methods:
Remarks:

Conclusions**Data Quality**

Reliability: Reliable without restriction Remarks:

References

Notox Project No. 289845

Other

D. Genetic Toxicity – Chromosomal Aberrations

Test Substance

Test substance: Quino(2,3-b)acridine-7,14-dione,5,12-dihydro

Remarks:

Method

Method: OECD 473??
Test type: Cytogenetics Assay
GLP: ??
Year: 2001??
Species/strain: Mouse Lymphoma L5178Y Cells
Exposure period:
Remarks:

Results

Result: Negative
Genotoxic effects: Negative
Concentration tested: ?????ug/plate
Statistical methods:
Remarks:

Conclusions

Not mutagenic

Data Quality

Reliability: Reliable without restriction
Remarks:

References

CTFA Micronucleus in vivo and mouse lymphoma cell mutation
underway January, 2000

Other

E. Developmental Toxicity

Test Substance

Test substance:

Remarks:

See subchronic toxicity and absorption studies above.

Method

Method:

GLP:

Year:

Species/strain:

Sex:

Route of exposure:

Exposure levels:

Actual doses received:

Exposure period:

Duration of test:

Remarks:

Results

Maternal toxicity

NOEL:

NOEL for

teratogenicity:

NOEL for fetotoxicity:

Parental toxic

responses:

Fetal toxic responses

dose:

Statistical Methods:

Remarks:

Since available radiographic studies establish consistently no significant uptake or absorption from this substance, no further reproduction or developmental studies are planned.

Conclusions

Data Quality

Reliability:

Remarks:

References

Other

F. Toxicity to Reproduction

Test Substance

Test substance:

Remarks:

Method

Method:

GLP:

Year:

Species/strain:Sex:

Route of exposure:

Exposure levels:

Exposure period:

Duration of test:

Remarks:

Results

Maternal toxicity NOEL:

Parental toxic responses:

Fetal toxic responses dose:

Statistical Methods:

Remarks:

Conclusions

Data Quality

Reliability:

Remarks:

References

Other

Acute toxicity

Test substance: (1) Quino(2,3-b)acridine-7,14-dione,5,12-dihydro and (2) Quino(2,3-b)acridine-7,14-dione,5,12-dihydro-2,9-dimethyl

Remarks:

Method

Method: Skin irritation to the rabbit
Test type: Skin irritation
GLP: unknown
Year: (1)1992 (2) 1982
Species/strain: rabbitt
Route of exposure:
Dose levels:
Remarks:

Results

Value: negative
Deaths at each dose:
Remarks:

Conclusions**Data Quality**

Reliability: unassignable
Remarks:

References

(1) Dupont Haskell Report HLO 584-82
(2) MB Research Labs Project No. MB 92-1750CD

Other

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